REMARKS

Claims 49-91 were pending in the application. Claims 90-91 have been withdrawn from further consideration by the Examiner as being drawn to a non-elected invention. Accordingly, upon entry of this amendment, claims 49-91 will be pending in the application.

No new matter has been added. Amendment and/or cancellation of the claims should in no way be construed as an acquiescence to any of the Examiner's rejections and was done solely to more particularly point out and distinctly claim the subject matter that Applicants believe to be their invention in order to expedite prosecution. Applicants reserve the right to pursue the claims as originally filed in this or a separate application(s).

Applicants gratefully acknowledge the courtesy of a telephonic interview that took place between the Examiner and Applicants' attorney, Megan Williams, on Monday, October 2, 2006. In that conversation, the Examiner indicated agreement with Applicants' attorney that the rejection of the claims on the grounds of nonstatutory obviousness-type double patenting rejections would be overcome by a Response detailing the Restriction Requirement in the parent application. Based on the explanation provided below, Applicants submit that the claims are in condition for allowance.

Moreover, since the Restriction Requirement between methods of diagnosing Hepatitis C virus and kits for diagnosing HCV issued in the March 24, 2006 Office Action was conditioned on the non-allowance of the linking claims, *i.e.*, claim 49, Applicants respectfully submit that Applicants are entitled to the examination of claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s). As set forth in M.P.E.P. § 809.04

> [i]f a linking claim is allowed, the examiner must thereafter examine species if the linking claim is generic thereto, or he or she must examine the claims to the nonelected inventions that are linked to the elected invention by such allowed linking claim.

Accordingly, Applicants respectfully request that claims 90 and 91 be examined.

Election/Restriction

The Examiner acknowledges Applicants' election with traverse of Group I (claims 49-89), SEQ ID NO:1, and SEQ ID NO:4. Applicants gratefully acknowledge the Examiner's indication that the restriction requirement between SEQ ID NOs: 2, 3, 4, 5, 6, and 9 has been withdrawn and that a search will be conducted for claims 49-89 including SEQ ID NOs: 2, 3, 4, 5, 6, and 9.

Information Disclosure Statement

Applicants acknowledge the Examiner's indication that the Information Disclosure Statements submitted May 20, 2005 and December 5, 2003 have been considered by the Examiner.

Priority

The Examiner has acknowledged Applicants' claim for priority date based on the filing dates of U.S. Application No.: 09/719,277, filed April 13, 2001, now U.S. Patent No. 7,052, 830, which is a U.S. National Phase application of PCT/US99/12929, file June 9, 1999, which claims the benefit of U.S. Provisional Application Nos. 60/088,670, filed June 9, 1998, and 60/089,138, filed June 11, 1998. Applicants dispute the Examiner's indication that SEQ ID NO:9 is granted the priority date of April 13, 2001. SEQ ID NO:9 is the first sequence of Table 1 of the application and that sequence was present in the first provisional application. Accordingly, Applicants submit that SEQ ID NO:9 is entitled to the January 9, 1998 priority date.

Rejection of Claims 49-89 On the Grounds of Nonstatutory Obviousness-Type Double Patenting

The Examiner has rejected claims 49-89 on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-34 of U.S. Patent No. 7,052,830, in view of Deleys, *et al.*, U.S. Patent No. 5,922,532. The Examiner is of the opinion that

> [c]laims 49-89 are drawn to a method of diagnosing HCV infection, comprising contacting an isolated, purified, or synthetic polypeptide comprising an amino acid sequence of at least 8 amino acids in length encoded by HCV comprising a nucleotide sequence corresponding to SEQ

> ID NO: 1 with a biological sample from a subject, and determining the presence or absence of an antibody, wherein presence of the antibody indicates infection with HCV. The polypeptides used in the currently claimed method of diagnosing HCV are SEQ ID NO: 2, 3, 4, 5, 6, and 9.

The Examiner continues:

> Claims 1-34 of US Patent No 7,052,830 teach a method of diagnosing HCV infection, comprising contacting a biological sample from a subject with an antibody that specifically binds to a polypeptide comprising an amino acid sequence of at least 8 amino acids in length encoded by HCV comprising a nucleotide sequence corresponding to SEQ ID NO: 1, determining the presence or absence of polypeptide, wherein presence of polypeptide indicates infection with HCV. The polypeptides to be detected in a sample are SEQ ID NO: 2, 3, 4, 5, 6, and 9.
>
> Thus, the polypeptides represented by SEQ ID NO: 2, 3, 4, 5, 6, and 9 recited in claims 1-34 of US Patent No 7,052,830, which are detected in a biological sample in a method of diagnosing HCV infection are identical to the polypeptides of SEQ ID NO: 2, 3, 4, 5, 6, and 9 used for detection of an antibody in a biological sample in the currently claimed method. The currently claimed method and the method taught in the US Patent No 7,052,830 are directed to diagnosing HCV infection. The difference between the two methods is that in the currently claimed method, the antibody specifically binding to SEQ ID NO: 2, 3, 4, 5, 6, and 9 is being detected in a biological sample, and in the method of the US Patent No 7,052,830 the polypeptides of SEQ ID NO: 2, 3, 4, 5, 6, and 9 are being detected in a biological sample using an antibody that specifically binds the said polypeptides.

Applicants respectfully traverse the foregoing rejection for at least the following reasons. As stated in M.P.E.P. § 804.01

> 35 U.S.C. § 121 authorizes the Director to restrict the claims in a patent application to a single invention when independent and distinct inventions are presented for examination. The third sentence of 35 U.S.C. § 121 prohibits the use of a patent issuing on an application with respect to which a requirement for restriction has been made, or on an application filed as a result of such a requirement, as a reference against any divisional application, if the divisional application is filed before the issuance of the patent. The 35 U.S.C. § 121 prohibition applies only where the Office has made a requirement for restriction. The prohibition does not apply where the divisional application was voluntarily filed by the applicant and not in response to an Office requirement for restriction.

Applicants submit that the Restriction Requirement issued by the Examiner in the parent application on September 6, 2002 (U.S. Application No.: 09/719,277, now U.S. Patent No.: 7.052, 830) restricted the claims to methods of diagnosing HCV infection, comprising contacting a biological sample from a subject with an antibody that specifically binds to a polypeptide comprising an amino acid sequence of at least 8 amino acids in length encoded by HCV comprising a nucleotide sequence corresponding to SEQ ID NO: 1, determining the presence or absence of polypeptide, wherein presence of polypeptide indicates infection with HCV (Group VIII) and methods of diagnosing HCV infection, comprising contacting an isolated, purified, or synthetic polypeptide comprising an amino acid sequence of at least 8 amino acids in length encoded by HCV comprising a nucleotide sequence corresponding to SEQ ID NO: 1 with a biological sample from a subject, and determining the presence or absence of an antibody, wherein presence of the antibody indicates infection with HCV (Group VI). The claims of Group VIII were prosecuted to allowance in the parent application, and the claims of the instant application are directed to the claims of Group VI. Given that the instant application is a divisional of the parent application, rejection of the instant claims on the grounds of nonstatutory obviousness-type double patenting over the parent application is improper.

Applicants submitted an Amendment to the Office May 20, 2005 amended the specification to designate the instant application as a divisional application. Applicants also submit a Supplemental Application Data Sheet concurrently herewith.

Applicants further point out that the Deleys, *et al.*, reference cited by the Examiner fails to provide any teaching or suggestion that alternate reading frame HCV polypeptides could be used in methods of detecting HCV infection and, therefore, fails to render the claimed invention obvious.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw this rejection of the claims.

SUMMARY

In view of the above amendments, Applicants believe that the present application is in condition for allowance. If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

Dated: October 6, 2006

Respectfully submitted,

By _____

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